propharma

ProPharma offers GMP and GDP compliance services from clinical development to commercial distribution of the products' lifecycle.

INCREASING LEVEL OF PRODUCT QUALITY REQUIREMENTS

CLINICAL TRIALS PHASES

Contracted QP services for IMP supplies.

MARKETING AUTHORISATION SUBMISSIONS

- API and excipient supplier audits to support QP declarations.
- Selecting and approving third party analytical testing laboratories.
- Process and analytical transfers.
- Selecting and approving third party vendors for contract storage and distribution.
- Technical agreement generation/review between client and all vendors.

COMMERCIAL MANUFACTURING

On-going GMP/GDP Regulatory Compliance Support

- GMP/GDP Quality Assurance support.
- Contracted QP services.
- Act as contracted RP for MIA holder that has contracted wholesaler distributor.
- Due diligence audits prior to regulatory audits.
- Support for GMP training.

DISTRIBUTION

END OF PRODUCT LIFECYCLE

CASE STUDY

MHRA inspection at overseas client's manufacturing site

ProPharma's Compliance and Quality are pleased to announce the positive outcome of the first on-site GMP regulatory audit, by UK's Medicines and Healthcare products Regulatory Agency (MHRA), of an overseas client in Bangladesh in July 2017. Our Compliance and Quality expert undertook a pre-audit readiness gap analysis inspection and subsequently returned to the site during the MHRA audit. The MHRA inspection resulted in no Critical nor any Major observations being raised.

Prior to resumption of formal on-site audits in Bangladesh, by MHRA. We had provided support to the same client by liaising with the VMD and MHRA Inspectorate's Risk, Control and Governance Unit for renew of the expiring VMD GMP certificate and granting of a MHRA GMP certificate following a desktop assessment.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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